

REMARKS

In response to the Official Action of May 6, 2009, Figure 4 has been amended to overcome the objection as noted at section 2 of the Official Action, claims 1-3, 6-11, 13 and 14 have been amended, claims 4, 5, 12, 15 and 16 have been cancelled and claim 17 newly presented. Support for new claim 17 is found in the application as originally filed, including Figure 4 and the supporting description in the specification at page 6, lines 1-4. Claim 1 has been amended to include the feature of claim 4 (which is now cancelled). The preamble of claim 1 has been amended to recite a dispenser for a gaseous, gas borne or droplet substance comprising a source of the substance, wherein said substance comprises medicament and propellant and said source comprises a reservoir and a release valve. Support for this amendment is found in the original application as filed, including claim 16. It is also supported by page 2, lines 5-8 which make clear that the source is an "aerosol valve can" and at page 4, line 31-page 5, line 2. It is also supported by Figures 1-4 which show such a dispenser. Such dispensers are typically called "inhalers" in the relevant art as distinguished from "nebulizers", that is, a device that has a medicament in a container separate from the source of gas to "atomize" the medicament. No new matter is added.

Drawings

At section 1, the drawings are objected to under 37 CFR 1.83(a) with regard to a feature recited in claim 12. Claim 12 has been cancelled and therefore no claim amendment is required in response to this section of the Office Action. At section 2, Figure 4 is objected to for listing reference numeral 224 but with no recitation in the specification. A corrected drawing sheet is submitted deleting the reference numeral 224 and thus the objection to Figure 4 is overcome.

Claim Objections

At section 3, claims 15 and 16 are objected to as being of improper dependent form. This objection is overcome since claim 15 and 16 are cancelled.

Claim Rejections 35 U.S.C. §112

At sections 5-7, claims 5 and 12 are rejected under 35 U.S.C. §112 second paragraph as being indefinite. Claims 5 and 12 are cancelled and therefore this rejection is moot. At section 8, claim 12 (the Office meant to refer to claim 13), is rejected with respect to the limitation “wherein the insert is parallel”. Claim 13 has been amended to indicate that the insert includes a uniform cross-section as shown in Figure 4. Therefore, the rejection of claim 13 is believed to be overcome.

Claim Rejections 35 U.S.C. §102

At section 10, claims 1, 2, 6-9, 11 and 12 are rejected under 35 U.S.C. §102(b) as being anticipated in view of U.S. Patent No. 3,001,524, Maison et al. (hereinafter Maison). With respect to claim 1 it is asserted that Maison shows a reservoir for a source of a gaseous, gas borne or droplet substance to be used in a dispenser comprising a major and minor portion with the features thereof as set forth in claim 1. Claim 1 has been amended to overcome this rejection as well as the rejection of claim 1 at section 11 as anticipated in view of U.S. Patent No. 5,878,917, Reinhard et al., and at section 12 as anticipated in view of U.S. Patent No. 5,086,765, Levine.

With respect to Maison, it is respectfully submitted that amended claim 1 is not anticipated since Maison does not disclose a reservoir wherein a minor portion is at the opposite end of the source of the substance with respect to a release valve, wherein the claim is defined as having a source comprising a reservoir and a release valve, wherein the reservoir has a minor portion at the opposite end of the source from the release valve. Rather as shown in the figures of Maison, such as Figure 4, the minor portion is at the valve end itself. This is also seen in Figures 2 and 3 of Maison. These figures show both ends of the reservoir and the end that is narrower (and therefore the minor portion) is at the valve end. Furthermore, claim 1 has been amended to incorporate the features of claim 4. The Office did not reject claim 4 as anticipated by Maison.

Similarly, with regard to Reinhard, the same arguments as set forth above apply. Reinhard discloses conventional sources wherein the narrower portion (that is the minor portion)

of the reservoir is at the valve end to facilitate its attachment to the valve. This is clearly seen in Figures 1-3 of Reinhard. Consequently, amended claim 1 is not anticipated by Reinhard.

It is only with regard to Levine that the Office asserts that the features of claim 4 are anticipated. Levine relates to nebulizers, while the present invention is specifically directed to a dispenser for gaseous, gas borne or droplet substance comprising a source of the substance wherein the substance comprises medicament and propellant and said source comprises a reservoir. Support for this amendment is found in the original application as filed including claim 16 as well as in the specification at page 4, line 31- page 5, line 2.

Levine on the other hand relates to nebulizers, not to a dispenser as disclosed in amended claim 1, which is generally considered to be an “inhaler,” that is, a device with both the medicament (droplet substance) as well as the propellant for dispensing thereof in the same reservoir. In Levine, the medicament is present in vial 86 and there exists a separate source of gas fed in via inlet 78 (see figures 1-3 of Levine). Thus, an important difference between the dispenser of the present invention and a nebulizer as disclosed in Levine is that in the dispenser of the present invention, the medicament is stored in the form of a pressurized liquid which forms an aerosol upon release, whereas in nebulizers, the gas source is separate. As a result, medicament reservoirs of nebulizers are typically not pressurized, as distinguished from the present invention where the reservoir contains not only a liquid medicament but also gas propellant liable to cause the glass to explode if broken (see page 4, line 31-page 5, line 2). It is therefore respectfully submitted that amended claim 1 is also not anticipated by Levine.

Furthermore, it is respectfully submitted that amended claim 1 is not suggested by any of the cited references. In particular the underlying concept of the present invention is that the source for the disclosed dispenser (e.g. for metered dose dispensers), can be provided that allow easy estimation of the number doses remaining in the source as the substance is close to exhaustion. Such sources are advantageous because they allow users of such dispensers to know when they are likely to need a new dispenser.

As discussed above, in relation to the anticipation rejection, neither Maison nor Reinhard is concerned with the provision of such dispensers comprising such a source. Rather, the sources

described in both of these references are conventional cans having a neck which slightly narrows at the valve end. There is nothing whatsoever in either of these references that provides to a person of ordinary skill in the art a motivation to redesign the source *per se* to facilitate the determination of the quantity of substance remaining therein as it approaches exhaustion. Accordingly, applicant respectfully submits that amended claim 1 is not suggested by Maison or Reinhard.

With respect to Levine, as discussed above, it is directed to nebulizers rather than dispensers as described herein. The design of nebulizers and the way in which they are used is different from such dispensers as disclosed and claimed herein. As discussed in Levine at columns 4 and 5, its nebulizers have a siphon tube 136 specifically selected to minimize the residual medication remaining in the vile at the end of the patient's treatment. This indicates that the nebulizer is designed to deliver the entire contents of a vile during a single treatment. The ability to measure the medicament in a nebulizer reservoir is therefore most important when setting up the nebulizer for use in a treatment, rather than for determining the number of doses of medicament remaining at any given time after the reservoir is initially filled.

More significantly, Levine teaches at column 4, lines 14-16 that the reason vile 86 tapers to form an inverted cone is to maximize the efficient use of the medicament. In other words, there is no teaching in Levine that the tapered shape of the vile is in any way related to being able to determine the amount of substance left therein, especially as the source approaches exhaustion. Rather, it is taught that the tapered shape enables the majority of medicament to be delivered. A person of ordinary skill in the art upon reviewing Levine would not apply the teaching therein to a dispenser as disclosed and claimed in the present application.

In a dispenser, such as that set forth in amended claim 1, the medicament typically spills away from the tapered end of the source toward the valve end during use and hence the shape of the end opposite the valve has no impact with respect to the efficiency of use of the medicament. Accordingly, there is no motivation whatsoever for a person of ordinary skill in the art upon review of Levine to employ the tapered shape of the vile disclosed therein for use with the dispenser as set forth in amended claim 1.

Moreover, at column 4, lines 16-18 of Levine, it is taught that vile 86 "is graduated as shown at 94 for accurate measure of medication." A person of ordinary skill in the art reading this portion of Levine and wanting to improve the estimation of dosage remaining in a dispenser as claimed herein would therefore provide a number of markings on the source. In other words, the teaching of Levine with respect to increasing the ability to estimate the amount of medicament present in a vile leads a person of ordinary skill in the art away from the present invention as claimed. In view of the foregoing, it is respectfully submitted that amended claim 1 is distinguished over Levine.

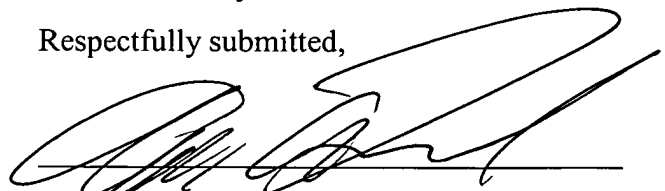
In view of the foregoing it is respectfully submitted that claims 1, 2, 6-9 and 11 are not anticipated or suggested by Maison, that claims 1 and 6-8 are not anticipated or suggested by Reinhard, and that claims 1, 3, 9, 11, 13 and 14 are not anticipated or suggested by Levine.

Claim Rejections 35 U.S.C. §103

At section 15, claim 10 is rejected under 35 U.S.C. §103(a) as unpatentable over Maison in view of U.S. Patent No. 3,506,004, Mann et al. Claim 10 ultimately depends from amended claim 1 and is believed to be allowable at least in view of such dependency.

In view of the foregoing, it is therefore respectfully submitted that the present application as amended is in condition for allowance and such action is earnestly solicited.

Respectfully submitted,



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